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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,234	08/27/2003	Nobuko Uchida	17810-518 (SCI-18)	6206

30623 7590 04/20/2006

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,234	UCHIDA ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *18-20 and 30-43* is/are withdrawn from consideration.

5)☒ Claim(s) *14,17,23-27 and 29* is/are allowed.

6)☒ Claim(s) *1-13,15,16,21,22 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I (claims 1-17 & 21-29) in Paper No. 2/01/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Claims 18-20 & 30-43.are withdrawn from further consideration by the examiner, 37CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 2/01/06.

Allowable Subject Matter

2. Claims 14, 17, 23-27 & 29 are allowed.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 & 13 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The appropriate ATCC numbers and required Deposit information critical or essential to the practice of the invention, as it relates to monoclonal antibodies SC20 (8G1.7), but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available, the enablement requirements of 35 USC §112, first paragraph, may be satisfied by a deposit of the material. See 37 CFR 1.802.

The specification lacks sufficient deposit information for the "novel" monoclonal antibody SC20 (8G1.7). Because this undefined monoclonal antibody is unknown, and therefore, publicly not available or can reproducibly isolated from nature without undue experimentation, a suitable deposit for patent purposes is required. See M.P.E.P. 608.01(p)(C). It is noted that U.S. Patent 5,843,633 describes monoclonal antibody AC133, which was deposited as ATCC #: HB12346 (e.g., see page 7 of the specification).

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

Amendment of the specification on page 21 to recite the date of deposits to the ATCC of SC20 (8G1.7) (i.e., PTA-993 & PTA-994), as well as a statement that all restriction will be "irrevocably removed" should obviate this rejection.

4. Claims 1-10, 12, 15-16, 21-22 & 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a population of enriched human CNS stem cells using identifiable/deposited antibodies, does not reasonably provide enablement for methods of isolating enriched populations of human CNS stem cells using unknown or uncharacterized "reagent[s] that specifically binds to the CD49f antigen", and/or that no longer bind to a CD24 antigen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification proposes a method of producing a population of enriched human CNS stem cells by enriching for CNS stem cells that bind to the monoclonal antibodies GoH3 and 4F10, which recognizes the antigen CD49f. Monoclonal antibody, AC133, from U.S. Patent 5,833,633, is also disclosed to be specific for stem/progenitor cells (e.g., see pages 14 & 24 of the specification). Thus, use of these known and obtainable monoclonal antibodies should select for any neural stem/ progenitor cells contained within a neural cell culture.

In contrast, base claims 1, 10, 16 & 29 putatively use any "monoclonal antibody that binds CD49f" or to CD133, or to CD24, in which no "reagent" that accomplishes such, except

for monoclonal antibodies, GoH3 and 4F10, AC133 and SC111, and Sc20, respectively, are known in the art. In other words, the mere mention of a antigenic site, alone, sets forth no structural characterization and little functional characteristics for determining when the skilled artisan is in possession of this required monoclonal antibody products for making and using the instant invention. Thus, an invitation for others to discover how to make and use the currently claimed invention based upon the limited guidance provided within the instant specification does not reasonably enable the currently claimed invention, because it would require undue experimentation for those skilled in the art to discover what structurally constitutes the monoclonal antibodies required to practice the claimed invention.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c).

Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 4 recites the broad recitation "flow cytometry", followed by the recitation of "(fluorescence activate cell sorting)", which is the narrower statement of the range/limitation.

6. Claims 7 & 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In that SC20 appears to be a monoclonal antibody designation, versus a well-known antigen designation, claim 7 is indefinite. Additionally, although monoclonal antibody AC133 appears to be "**the** anti-CD133 monoclonal antibody", page 15 also lists putative monoclonal antibody SC111 as binding to CD133. Therefore, it is unclear what "**the** anti-CD133 monoclonal antibody" actually constitutes.

7. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, claims 1 & 10 are incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: selection of "progenitors, or combination thereof", as recited in the preamble. In other words, step b) only results in enrichment "for human CNS-SC", versus "progenitors, or combination thereof".

8. Claims 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

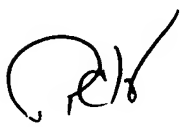
It is ambiguous and contradictory what constitutes a "reagent", when the claims and specification alternatively appear to contemplate that it is the monoclonal antibodies, GoH3 and 4F10, that are "the reagent[s]" useful for enriching for CNS stem cells. In addition, it is ambiguous when a "reagent *specifically* binds...", versus no longer "s*pecifically* binds", in that the term "specifically binds" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention; thereby, rendering this claim further indefinite.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
April 13, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER